

Attorney Docket No.: **DEX-0184**
Inventors: **Roberto A. Macina**
Serial No.: **09/806,311**
Filing Date: **July 18, 2001**
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REMARKS

Claim 1 is pending in the instant application. Claim 1 has been rejected. Reconsideration is respectfully requested in light of the following remarks.

I. Amendment to Specification

In accordance with the Examiner's request, Applicants have amended the first line of the specification to delete the phrase in the priority claim regarding incorporation by reference.

II. Rejection of Claims 1 under 35 U.S.C. § 112, first paragraph

Claim 1 has been rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The Examiner has acknowledged the claim to be enabled for a method of detecting the presence of cancer of the stomach or small intestine by detection of mRNA levels in a sample of stomach or small intestine with an increase in measured levels versus normal matched control samples. The Examiner suggests, however, that the specification is not enabled for detection of SEQ ID NO:2 in the sample or detection in just any tissue.

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants are providing herewith a copy of a poster presented at Cambridge Healthtech Institute's Eleventh

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Annual Molecular Medicine Tri-Conference and Exposition on March 23-26, 2004 at the Moscone Center in San Francisco confirming that mRNA expression levels of Cln101 (referred to as CC2 in the instant specification) correlate with protein (SEQ ID NO:2) expression levels and that Cln101 or CC2 protein expression was detectable not only in the cancer tissues but in other samples, and in particular serum. In addition to a copy of the complete poster presentation, Applicants are providing herewith an enlarged copy of the graph from the poster with confirming evidence of Cln101 (CC2) protein expression in cancer serum samples.

This poster presentation confirms teachings in the instant specification at page 4, lines 1-16, page 7, line 19 through page 8, line 3, page 11, line 15, through page 12, line 19, and page 13, line 29, through page 14, line 12 regarding expression levels of SEQ ID NO:2 being a diagnostic marker for cancer and teachings in the instant specification at page 14, lines 13-20 that CC2 is detectable in cells, tissues and bodily fluids.

Thus, since Applicants have now provided evidence of the protein's expression including the correlation to a diseases state, one of skill in the art can predictably use the polypeptides in a diagnostic setting in accordance with the

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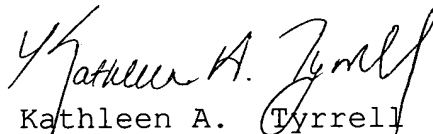
teachings of the specification without any undue experimentation.

Withdrawal of this rejection under 35 U.S.C. § 112, first paragraph is therefore respectfully requested.

III. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,



Kathleen A. Tyrrell
Registration No. 38,350

Date: **July 28, 2004**

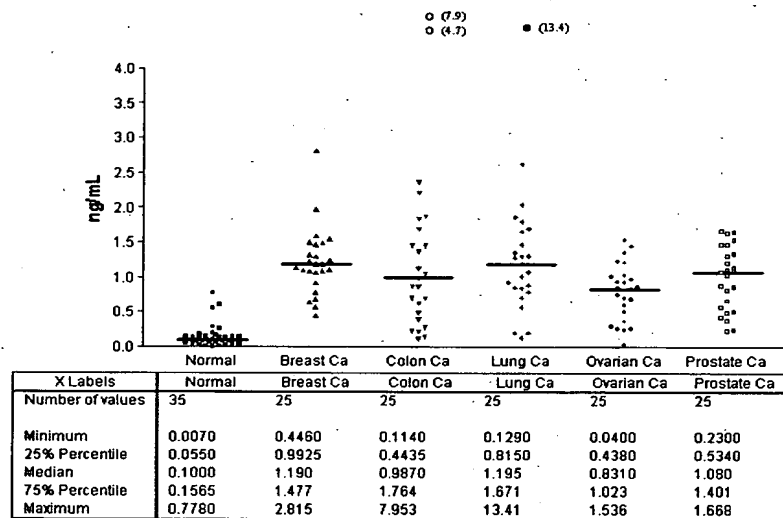
LICATA & TYRRELL P.C.
66 E. Main Street
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We thank Ai-Li-Mei Chen for obtaining the Full-length clones used in this study. We also thank the Protein Science and Antibody groups for the generation of key reagents.

Western immunoblot with antibody against tagged protein

Expression

Cln101 in Cancer Serum Samples



The figure shows levels of Cln101 in normal and cancer serum. Thirty five serum samples from normal donors, and 25 serum samples from patients with 5 different cancer type were tested with Cln101 ELISA. The data shows that Cln101 is detectable in low levels in serum and that the serum Cln101 levels are significantly higher in cancer patients when compared to normal controls.